

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Application Number	10/829,618
Filing Date	April 20, 2004
Inventor(s)	Dudley et al.
Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

U.S. PATENT DOCUMENTS

Exam. Initial.	No.	Document No.	Issue/Publication Date	Applicant(s)
	1.	4861764	08-29-1989	Samour et al.
	2.	5152997	10-06-1992	Ebert et al.
	3.	5231087	07-27-1993	Thornfeldt
	4.	5550107	08-27-1996	Labrie
	5.	5643899	07-01-1997	Elias et al.
	6.	5723114	03-03-1998	Thornfeldt et al.
	7.	5730987	03-24-1998	Omar
	8.	5760096	06-02-1998	Thornfeldt et al.
	9.	5788983	08-04-1998	Chien et al.
	10.	5955455	09-21-1999	Labrie
	11.	5968919	10-19-1999	Samour et al.
	12.	6019997	02-01-2000	Scholz et al.
	13.	6200591	03-13-2010	Hussain et al.
	14.	6319913	11-20-2001	Mak, et al.
	15.	6503894	01-07-2003	Dudley, R.E.
	16.	6562369	05-13-2003	Luo et al.
	17.	6562370	05-13-2003	Luo et al.

Examiner Signature		Date Considered	
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U.S. PATENT DOCUMENTS

Exam. Initial.	No.	Document No.	Issue/Publication Date	Applicant(s)
	18.	6586000	07-01-2003	Luo et al.
	19.	7097853	08-29-2006	Garbe et al.
	20.	7320968	01-22-2008	Gyurik
	21.	20030022877	01-20-2003	Dudley
	22.	20040110732	06-10-2004	Masini-Eteve et al.
	23.	20030027804	02-06-2003	Van der Hoop Roland Gerritsen
	24.	20040072810	04-15-2004	Masini-Eteve et al.
	25.	20050020552	01-27-2005	Aschkenasy et al.
	26.	20050113353	05-26-2005	Dudley et al.

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FOREIGN PATENT DOCUMENTS

Exam Initial	No.	Document No.	Publication Date	Country
	27.	EP1634583	03-15-2006	Salin-Drouin
	28.	WO0217926	03-07-2002	UNIMED Pharmaceuticals
	29.	WO9325168	12-23-1993	Theratech, Inc.
	30.	WO9627372	09-12-1996	International Medical Innovations, Inc.
	31.	WO9831368	07-23-1998	Johnson
	32.	WO9924041	05-20-1999	Mak, et al.

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RELATED AND CO-PENDING U.S. PATENT APPLICATIONS

Exam Initial	No.	Application Serial No.	Filing Date
	33.	09/651777 (now US 6,503,894)	08-30-2000
	34.	09/703753 (abandoned)	11-01-2000
	35.	09/892981 (abandoned)	06-27-2001
	36.	10/033101 (abandoned)	10-19-2001
	37.	10/046454 (abandoned)	10-19-2001
	38.	10/098232 (abandoned)	03-15-2002
	39.	10/099725 (abandoned)	03-15-2002
	40.	10/153468 (abandoned)	05-21-2002
	41.	10/248267 (abandoned)	01-03-2003
	42.	10/273484 (abandoned)	10-18-2002
	43.	10/436380 (now US 7,611,727)	05-12-2003
	44.	10/456868	06-06-2003
	45.	10/787071 (abandoned)	02-25-2004
	46.	10/825540 (abandoned)	04-15-2004
	47.	10/828678 (abandoned)	04-20-2004
	48.	10/867435	06-14-2004

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Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

49.	10/867445	06-14-2004
50.	10/925421	08-24-2004
51.	11/399642	04-06-2006
52.	11/402682	04-11-2006
53.	11/402986	04-11-2006
54.	11/549083	10-12-2006
55.	11/662339	09-24-2007
56.	11/925421	10-26-2007
57.	12/052337	03-20-2008
58.	12/543541	08-19-2009
59.	12/609473	10-30-2009

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Attorney Docket Number	003168.1043

OFFICE ACTIONS AND RESPONSES IN CO-PENDING U.S. PATENT APPLICATIONS

Exam Initial	No.	Application Serial No.	Date of Office Action or Response
	60.	11/402986	05-14-2010 Final Office Action
	61.	11/402986	02-22-2010 Response to Non-Final Office Action
	62.	11/402986	08-20-2009 Non-Final Office Action
	63.	11/402986	05-15-2009 Response to Non-Final Office Action
	64.	11/402986	11-17-2008 Non-Final Office Action
	65.	11/402682	03-17-2010 RCE and Response to Final Office Action
	66.	11/402682	09-17-2009 Final Office Action
	67.	11/402682	06-02-2009 Response to Non-Final Office Action
	68.	11/402682	12-02-2008 Non-Final Office Action
	69.	11/399642	10-15-2010 Final Office Action
	70.	11/399642	08-09-2010 Response to Non-Final Office Action
	71.	11/399642	02-08-2010 Non-Final Office Action -
	72.	11/399642	11-16-2009 Response to Non-Final Office Action
	73.	11/399642	05-14-2009 Final Office Action
	74.	11/549083	09-27-2010 RCE and Response to Final Office Action
	75.	11/549083	03-25-2010 Final Office Action

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76.	11/549083	01-08-2010 Response to Notice of Non-Compliant Amendment
77.	11/549083	10-13-2009 Response to Non-Final Office Action
78.	11/549083	10-13-2009 Declaration of Norman Weiner
79.	11/549083	06-22-2009 Non-Final Office Action
80.	11/549083	04-01-2009 RCE and Response to Final Office Action
81.	11/549083	01-14-2009 Final Office Action
82.	11/549083	10-23-2008 Declaration of Norman Weiner
83.	11/549083	10-23-2008 Response to Non-Final Office Action
84.	11/549083	10-23-2008 Declaration of Drs. Ramana Malladi and Jodi Miller (37 CFR 1.131)
85.	11/549083	10-23-2008 Petition to Correct Inventorship
86.	11/549083	04-24-2008 Non-Final Office Action
87.	11/549083	12-06-2007 Non-Final Office Action
88.	12/052337	09-29-2010 RCE and Response to Final Office Action
89.	12/052337	03-29-2010 Final Office Action
90.	12/052337	11-16-2009 Response to Non-Final Office Action
91.	12/052337	05-15-2009 Non-Final Office Action
92.	09/892981	12-11-2006 Final Office Action
93.	09/892981	09-28-2006 Response to Non-Final Office Action

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94.	09/892981	03-28-2006 Non-Final Office Action
95.	09/892981	12-16-2005 RCE and Response to Final Office Action
96.	09/892981	06-21-2005 Final Office Action
97.	09/892981	04-08-2005 Response to Non-Final Office Action
98.	09/892981	03-15-2005 Notice of Non-Responsive Amendment
99.	09/892981	02-24-2005 Response to Non-Final Office Action
100.	09/892981	08-25-2004 Non-Final Office Action
101.	09/892981	04-16-2004 RCE and Response to Final Office Action
102.	09/892981	02-09-2004 Advisory Action
103.	09/892981	12-16-2003 Response to Final Office Action
104.	09/892981	10-16-2003 Final Office Action
105.	09/892981	07-25-2003 Response to Non-Final Office Action
106.	09/892981	02-26-2003 Non-Final Office Action
107.	09/892981	11-26-2002 RCE and Response to Final Office Action
108.	09/892981	08-27-2002 Final Office Action
109.	09/892981	06-07-2002 Response to Non-Final Office Action
110.	09/892981	02-08-2002 Non-Final Office Action
111.	10/099725	01-29-2003 Office Action
112.	10/099725	10-01-2002 Office Action

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113.	10/456868	01-12-2006 Non-final Office Action
114.	10/456868	04-25-2006 Response to Non-Final Office Action
115.	10/456868	06-28-2006 Final Office Action
116.	10/456868	11-28-2006 Declaration of Valerie Masini-Eteve
117.	10/456868	11-28-2006 Response to Final Office Action
118.	10/456868	04-25-2007 RCE and Response to Final Office Action
119.	10/456868	04-25-2007 Declaration of Valerie Masini-Eteve
120.	10/456868	08-05-2009 Non-Final Office Action
121.	10/456868	02-04-2010 Declaration under 37 CFR 1.131
122.	10/456868	02-04-2010 Response to Non-Final Office Action
123.	10/456868	05-11-2010 Non-Final Office Action
124.	10/456868	08-11-2010 Response to Non-final Office Action
125.	10/456868	10-27-2010 Non-Final Office Action
126.	10/099725	01-29-2003 Non-Final Office Action
127.	10/436380	08-05-2009 Response to Amendment under Rule 312
128.	10/436380	07-23-2009 Amendment After Notice of Allowance
129.	10/436380	05-13-2009 Notice of Allowance
130.	10/436380	04-22-2009 Response to Final Office Action
131.	10/436380	01-23-2009 Final Office Action

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	132.	10/436380	10-28-2008 Response to Non-Final Office Action
	133.	10/436380	10-28-2008 Declaration of Russel Potts
	134.	10/436380	10-28-2008 Declaration of Olivier Raux
	135.	10/436380	05-28-2008 Non-Final Office Action
	136.	10/436380	05-02-2008 RCE and Response to final Office Action
	137.	10/436380	01-02-2008 Final Office Action
	138.	10/436380	11-19-2007 Response to Non-Final Office Action
	139.	10/436380	07-17-2007 Non-Final Office Action
	140.	10/436380	01-03-2007 Non-Final Office Action
	141.	10/436380	07-03-2006 Non-Final Office Action
	142.	11/662339	10-04-2010 Response to Non-Final Office Action
	143.	11/662339	06-14-2010 Non-Final Office Action
	144.	11/662339	02-22-2010 Response to Non-Final Office Action
	145.	11/662339	09-22-2009 Non-Final Office Action
	146.	11/662339	05-29-2009 Response to Non-Final Office Action
	147.	11/662339	02-03-2009 Non-Final Office Action
	148.	10/099725	01-29-2003 Non-Final Office Action
	149.	10/099725	09-29-2003 Notice of Abandonment
	150.	09/651777	06-19-2001 Non-Final Rejection

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	151.	09/651777	10-29-2001 Response after Non-Final Action
	152.	09/651777	10-29-2001 Declaration of Jean-Louis Anspach
	153.	09/651777	12-21-2001 Supplemental Amendment
	154.	09/651777	01-16-2002 Supplemental Amendment
	155.	09/651777	02-08-2002 Supplemental Amendment II
	156.	09/651777	02-06-2002 Declaration of Robert E. Dudley dated (submitted with the Supplemental Amendment II dated 02-08-2002)
	157.	09/651777	04-01-2002 Letter in response to 03-28-2002 Examiner Interview
	158.	09/651777	05-07-2002 Non-Final Rejection
	159.	09/651777	05-20-2002 Response after Non-Final Action
	160.	09/651777	07-23-2002 Supplemental Response After Interview
	161.	09/651777	07-23-2002 Declaration of Michele Alm
	162.	09/651777	07-23-2002 Declaration of Sandy Faulkner
	163.	09/651777	07-24-2002 Supplemental Response
	164.	09/651777	08-01-2002 Supplemental Response
	165.	09/651777	08-20-2002 Protest under 37 CFR §1.291(a)
	166.	09/651777	08-13-2002 Notice of Allowance
	167.	09/651777	06-12-2003 Request for Certificate of Correction under 37 CFR §1.322 (2 pages of corrections)
	168.	09/651777	06-12-2003 Request for Certificate of Correction under 37 CFR

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			§1.323 (1 page of corrections)
	169.	09/651777	10-17-2003 Certificate of Correction
	170.	09/651777	11-29-2004 Petition to correct inventorship under 35 USC §256, 37 CFR §1.324, and M.P.E.P. §1481 (a certificate of correction is submitted)
	171.	09/651777	03-27-2007 Decision Granting Petition to Correct Inventorship under 37 CFR §1.324
	172.	09/651777	04-30-2007 Certificate of Correction
	173.	09/651777	05-22-2007 Certificate of Correction - Correction of Inventors
	174.	09/703753	04-24-2001 Non-Final Rejection
	175.	09/703753	08-24-2001 Response after Non-Final Action
	176.	09/703753	11-23-2001 Final Rejection
	177.	09/703753	02-22-2002 Notice of Appeal and Amendment/Argument after Notice of Appeal
	178.	09/703753	03-22-2002 Advisory Action
	179.	09/703753	06-05-2002 Non-Final Rejection
	180.	09/703753	10-21-2002 Response after Non-Final Action
	181.	09/703753	01-15-2003 Non-Final Rejection
	182.	09/703753	04-09-2003 Response after Non-Final Action
	183.	09/703753	06-19-2003 Response after Non-Final Action
	184.	09/703753	08-26-2003 Final Rejection

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	185.	10/046454	09-10-2002 Non-Final Rejection
	186.	10/046454	09-20-2002 Response after Non-Final Action
	187.	10/046454	12-09-2002 Supplemental amendment
	188.	10/046454	01-27-2003 Notice of Allowance
	189.	10/046454	06-13-2003 Request for Continued Examination (RCE), Petition to Withdraw, and Supplemental amendment
	190.	10/046454	06-18-2003 Petition Decision of Granted to Withdraw from Issue
	191.	10/046454	07-11-2003 Supplemental Amendment B
	192.	10/046454	10-16-2003 Non-Final Rejection
	193.	10/828678	06-25-2008 Non-Final Rejection
	194.	10/098232	07-31-2003 Preliminary Amendment
	195.	10/098232	10-20-2003 Non-Final Rejection
	196.	10/098232	11-14-2007 Request under Rule 48 correcting inventorship
	197.	10/825540	06-20-2008 Non-Final Rejection
	198.	10/153468	02-24-2004 Non-Final Rejection
	199.	10/153468	08-24-2004 Response after Non-Final Action
	200.	10/153468	11-17-2004 Final Rejection
	201.	10/867435	06-09-2008 Non-Final Rejection
	202.	10/867435	12-09-2008 Response after Non-Final Action

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	203.	10/867435	03-11-2009 Final Rejection
	204.	10/867435	09-11-2009 Request for Continued Examination and Amendment
	205.	10/867435	12-04-2009 Non-Final Rejection
	206.	10/867435	06-04-2010 Response after Non-Final Action
	207.	10/867435	08-13-2010 Final Rejection
	208.	10/867445	03-11-2008 Non-Final Rejection
	209.	10/867445	06-24-2008 Response after Non-Final Action
	210.	10/867445	10-10-2008 Non-Final Rejection
	211.	10/867445	04-10-2009 Response after Non-Final Action
	212.	10/867445	07-15-2009 Final Rejection
	213.	10/867445	12-14-2009 Request for Continued Examination and Amendment
	214.	10/867445	01-19-2010 Non-Final Rejection
	215.	10/867445	07-19-2010 Response after Non-Final Action
	216.	10/867445	09-24-2010 Final Rejection
	217.	10/787071	10-02-2007 Non-Final Rejection
	218.	10/787071	02-01-2008 Response after Non-Final Action
	219.	10/787071	05-29-2008 Final Rejection
	220.	10/531526	03-18-2008 Non-Final Rejection
	221.	10/531526	07-17-2008 Response after Non-Final Action

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222.	10/531526	11-17-2008 Final Rejection
223.	10/531526	05-12-2009 Request for Continued Examination (RCE) and Amendment
224.	10/531526	07-09-2009 Non-Final Rejection
225.	10/531526	12-08-2009 Response after Non-Final Action
226.	10/531526	02-22-2010 Final Rejection
227.	10/531526	08-20-2010 Request for Continued Examination (RCE) and Amendment
228.	10/033101	01-10-2003 Non-Final Rejection
229.	10/033101	05-12-2003 Response after Non-Final Action
230.	10/033101	06-03-2003 Supplemental Amendment and Request for Interview
231.	10/033101	06-30-2003 Supplemental Amendment B
232.	10/033101	10-21-2003 Final Rejection
233.	12/543541	08-19-2009 Petition for 12-month Accelerated Exam, Pre-examination search document; accelerated examination support document
234.	12/543541	12-07-2009 Petition for 12-month Accelerated Exam Decision -- Granted
235.	12/543541	01-28-2010 Examiner Interview Summary Record
236.	12/543541	02-02-2010 Applicants' comments to Examiner-initiated interview summary
237.	12/543541	02-05-2010 Non-Final Rejection

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Application Number	10/829,618
Filing Date	April 20, 2004
Inventor(s)	Dudley et al.
Art Unit	1627
Examiner Name	Jean-Louis, Samira
Attorney Docket Number	003168.1043

238.	12/543541	03-05-2010 Response after Non-Final Action
239.	12/543541	04-05-2010 Final Rejection
240.	12/543541	10-05-2010 Request for Continued Examination (RCE) and Amendment
241.	12/543541	11-09-2010 Non-Final Rejection
242.	10/829618	05-14-2008 Non-Final Rejection
243.	10/829618	11-13-2008 Response after Non-Final Action
244.	10/829618	02-05-2009 Non-Final Rejection
245.	10/829618	08-05-2009 Response after Non-Final Action
246.	10/829618	11-30-2009 Non-Final Rejection
247.	10/829618	06-01-2010 Response after Non-Final Action
248.	10/829618	08-11-2010 Notice of Allowance
249.	10/925421	11-24-2008 Non-Final Rejection
250.	10/925421	05-26-2009 Response after Non-Final Action
251.	10/925421	09-29-2009 Final Rejection
252.	10/925421	03-29-2010 Response after Final Action and RCE
253.	10/925421	10-12-2010 Non-Final Rejection
254.	10/248267	12-15-2003 Non-Final Rejection
255.	10/273484	12-15-2003 Non-Final Rejection

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SEARCH REPORTS AND OPPOSITIONS

Exam. Initial	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	256.	International Preliminary Examination Report – Application No. PCT/US2003/007910 (27 May 2004)
	257.	International Search Report – Application No. PCT/US2003/032597 (19 May 2004)
	258.	International Preliminary Examination Report – Application No. PCT/US2003/032597 (08 July 2004)
	259.	International Preliminary Report on Patentability I – Application No. PCT/US2006/013551 (29 May 2007)
	260.	International Search Report – Application No. PCT/US2001/27202 (29 January 2002)
	261.	International Search Report – Application No. PCT/US2003/007910 (17 October 2003)
	262.	International Search Report and Written Opinion– Application No. PCT/EP2006/003974 (04 September 2006)
	263.	International Search Report and Written Opinion– Application No. PCT/US2006/013551 (07 August 2006)
	264.	International Preliminary Report on Patentability I - Application No. PCT/EP2006/003974 (09 October 2007).
	265.	International Preliminary Report on Patentability I - Application No. PCT/US2006/040481 (16 April 2008).
	266.	International Search Report - Application No. PCT/US01/27199, Reference No. 01902267 (International Filing Date: 08/29/01).
	267.	International Search Report - Application No. PCT/US01/27205, Reference No. 01736544 (International Filing Date: 08/29/01).
	268.	International Search Report of PCT/US2006/040481 mailed July 13, 2007
	269.	Singapore Patent Application No. 200802644-5, Search Report and Written Opinion, December 2, 2009.
	270.	International Search Report, and International Preliminary Report on Patentability I – Application No. PCT/US2002/020141
	271.	International Search Report, Written Opinion and International Preliminary Report on Patentability I – Application No. PCT/US2006/013550

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	272.	International Search Report, Written Opinion and International Preliminary Report on Patentability I – Application No. PCT/EP2008/053372
	273.	European Search Report issued on 04/25/2002 in application number EP01403166 (corresponding to US 2003/0087885)
	274.	Search report for EP0672422, published 07-28-1994.
	275.	USPTO Word Mark Search on "CPE-215", uspto.gov (searched 10/21/02).
	276.	Written Opinion of the International Searching Authority of PCT/US2006/040481, July 13, 2007
	277.	Opposition in Venezuela VE000537/03
	278.	Opposition to CL1026-2007
	279.	Opposition to CO08036312
	280.	Opposition to ECSP088363
	281.	Response to Opposition to ECSP088363

OTHER DOCUMENTS (Non-patent literature)

Exam. Initial	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
	282.	Androgel® 1% Package Insert, Dec. 2000.
	283.	Asbill CS, et al., "Enhancement of transdermal drug delivery: chemical and physical approaches," Crit Rev Ther Drug Carrier Syst. (2000);17(6):621-58.
	284.	Aungst, "Structure/effect studies of fatty acid isomers as skin penetration enhancers and skin irritants," Pharmaceutical Research (1989); 6(3):244-247
	285.	Auxilium Pharmaceutical, Inc. Citizen's Petition Decision, August 26, 2009, Docket No. FDA-2009-P-0123.
	286.	Barrett-Connor, Elizabeth et al. Bioavailable Testosterone and Depressed Mood in Older

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Exam. Initial.	No.	Include name of Author, Title, Date, Pertinent Pages, Etc.
		Men: The Rancho Bernardo Study. J. Clinical Endocrinology and Metabolism (1999); 84(2):573-577.
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	288.	Griffin, J.E. "Hormonal Replacement Therapy at the Time of Expected Puberty in Patients With Gonadal Failure." The Endocrinologist (2003);13(3):211-213.
	289.	EL TRIBUNAL DE JUSTICIA DE LA COMUNIDAD ANDINA, October 27, 2000 (available at http://intranet.comunidadandina.org/Documentos/Procesos/21-ip-2000.doc)
	290.	Kanikkannan N, et al., "Structure-activity relationship of chemical penetration enhancers in transdermal drug delivery," Curr Med Chem. (2000) Jun;7(6):593-608.
	291.	Moreland, et al., "Sildenafil, A Novel Inhibitor of Phosphodiesterase Type 5 In Human Corpus Cavernosum Smooth Muscle Cells," Life Sciences (1998);62(20):PL309-318.
	292.	Swerdlloff RS, et al., "Long-term pharmacokinetics of transdermal testosterone gel in hypogonadal men," J Clin Endocrinol Metab. (2000) Dec;85(12):4500-10.
	293.	Wang et al. "Transdermal Testosterone Gel Improves Sexual Function, Mood, Muscle Strength, and Body Composition Parameters in Hypogonadal Men." J. Clin. Endocrin. Metab. (2000);85(8):2839-53.
	294.	Wang, et al., "Comparative Pharmacokinetics of Three Doses of Percutaneous Dihydrotestosterone Gel in Healthy Elderly Men - A Clinical Research Center Study," Journal Of Clinical Endocrinology And Metabolism (1998) Aug;83(8):2749-2757.
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	296.	Warnock et al., "Female Hypoactive sexual disorder: Case studies of physiologic androgen replacement," J. Sex and Marital Therapy (1999);25:175-182.
	297.	Webb et. al., "Sildenafil citrate and blood-pressure-lowering drugs: results of drug interaction studies with an organic nitrate and a calcium antagonist." American Journal of Cardiology(1999);83(5A):21C-28C.

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NY02-698301 I

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	298.	Webster's New Collegiate Dictionary. 2000. Definition of Prevention. pg. 1.
	299.	Williams AC and Barry BW, "Penetration enhancers," Adv Drug Deliv Rev. (2004) Mar 27;56(5):603-18.
	300.	Xie et. al., "Induction of high incidence of mammary tumour in female Noble rats with a combination of 17 β -oestradiol and testosterone " Carcinogenesis (1999); 20(6):1069-1078.

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